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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,197	08/14/2001	John R. Reynolds	41530/28293	1200

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

341-

Office Action Summary**Application No.**

09/929,197

Applicant(s)

REYNOLDS ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 and 39-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 and 39-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 04/01/04. Claims 1-37 and 39-53 are pending.

Claim Rejections - 35 USC § 112

1. The rejection of claims 17-26 and 38-51 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because:

Claim 17 is amended. Claim 17 no longer refer back to the Figure in the specification.

Claims 38 is cancelled and claim 39 is amended.

Claim 44 now recites method steps and also raises the issue of new matter.

NEW MATTER

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 44 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 44 as currently amended is directed to a process of preparing a burst electrode where the process involves depositing an electroactive polymer film containing various biologically active molecules on an electrode and the release of the various biologically active molecules exhibit non-Faradaic release. Applicants indicated that the amendment might be

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found in paragraph 43 of the instant disclosure. However, paragraph 43 does not describe deposition of electroactive polymer film containing biologically active molecules on an electrode.

Thus, the method step now recited in claim 44 is not found in paragraph 43 of the instant specification and therefore raises the issue of new matter.

Claim Rejections - 35 USC § 102

4. Claims 1-6, 10-14, 16-31, 36, 37 and 39-51 remain rejected under 35 U.S.C. 102(b) as being anticipated by Kinlen ("Controlled Drug And Biomolecule Release from Electroactive Host Polymer System," presented at American Chemical Society Meeting, Anaheim, California, March 1999).

Applicants argue that the Kinlen work does not disclose non-Faradaic release of biologically active molecules because Kinlen fails to specifically state that the release of the biologically active molecules is non-Faradaic. To this end applicants cite:

- 1) PPG Indus V. Guardian Indus Corp. 75 F.3d 1558, 1566 (Fed. Cir. 1996), 37 USPQ2d 1618
- 2) Ex parte Skinner, 2 USPQ2d 1788
- 3) In re Oelrich and Divigard, 212 USPQ 323
- 4) Schering Corp. v. Geneva Pharmaceuticals Inc., 67 USPQ2d 1664 (CA FC 2003)
- 5) In re Robertson 49 USPQ2d 1949 (2/25/1999) and
- 6) MPEP § 2112, which "places the burden on the office to provide evidence or scientific reasoning showing the novel characteristic was inherently present in the prior art."

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5. Applicants' arguments filed 04/01/04 have been fully considered but they are not persuasive.

The PPG Indus V. Guardian Indus Corp. 75 F.3d 1558, 1566 (Fed. Cir. 1996), 37 USPQ2d 1618 case, US Court of Appeals Fed. Circuit upheld the injunction, in favor of the appellee PPG Industries, Inc. over appellant Guardian Industries Corporation, by the Western District of Pennsylvania prohibiting "Guardian from making, using, or selling its own composition of solar glass."

In the Ex parte Skinner, 2 USPQ2d 1788 ruling, there appears to be a structural difference between the mold of the reference patent and the appellants mold and the difference results from the manner in which the appellants mold was constructed so that a certain degree of surface roughness of no more than about 12.5×10^{-8} meters, RMS was achieved. It was noted by the Board that the preparatory techniques of the appellant and the reference patent differed thereby producing structurally different products.

In the present case, there is no structural difference between the electrode composition and the composition of the reference. The instant electrode composition comprises electroactive polymer and biologically active ingredient. The electroactive polymer is defined in dependent claim 6 as comprising polypyrrole polymer and the biologically active ingredient is an anion (instant claim 2). Now, a composition such as the composition of the Kinlen reference where the composition comprises polypyrrole/salicylate system for loading and delivery of anionic biomolecules would naturally release the biomolecule in order to deliver the drug. Since both compositions are the same and both compositions are designed to deliver biologically active agents, the

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delivery from both compositions would occur according to the same release pattern and applicants have not shown why the release pattern from the reference composition would differ from the release pattern of the instant claims.

In the *In re Oelrich and Divigard*, 212 USPQ 323 situation, the claim in judgment defined a means that is responsive to movement and this means-function was not disclosed in the prior patent reference issued to same inventors.

This particular situation differs from the case in question since both compositions of the prior art and the examined claims are the same and release biologically active ingredients.

In the *In re Robertson* 49 USPQ2d 1949 (2/25/1999) situation, the third fastening means present in the claim in judgment is not present in the prior art reference.

In the present instance the drug delivery compositions are the same and thus the drug release patterns ought to be necessarily the same.

In the *Schering Corp. v. Geneva Pharmaceuticals Inc.*, 67 USPQ2d 1664 (CA FC 2003) situation, the court affirmed that the Loratidine patent anticipates the application that claims the metabolite of loratidine, descarboethoxyloratidine (DCL).

In the examined case, the instant delivery composition and that of the prior art reference are the same.

Regarding the MPEP citation, it is noted that no optimization is required for the composition of Kinlen to inherently release biologically active ingredients in a non-Faradaic release profile and the Examiner does not have to produce extrinsic evidence.

6. Claims 1, 3-15, 17, 19-24, 27-34, 36, 37, 39, 41 and 43-53 remain rejected under 35 U.S.C. 102(b) as being anticipated by Zhou et al. ("Electrochemically controlled binding and

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release of protonated dimethyldopamine and other cations from poly(N-methylpyrrole)/polyanion composite redox polymers,” J. Electroanalytical Chem., 261 (1989) pp 147-164).

Applicants argue that as with the Kinlen (Reynolds) and Pyo references, Zhou does not disclose burst release and that the release of Zhou appears to be Faradaic and that in the examined case, the potential total release occurs in the first and second burst. Applicants further state that the argument given for Kinlen and Pyo also applies to the Zhou case.

7. Applicants' arguments filed 04/01/04 have been fully considered but they are not persuasive.

Examiner's explanations and response provided for applicants' arguments against the Kinlen reference also applies here.

Regarding the release pattern of the Zhou composite delivery system, applicants presented no data supporting the position that although the Zhou's delivery system is comprised of the same polymeric carriers as the examined claims the Zhou's delivery exhibits Faradaic release pattern and the instant delivery system exhibits non-Faradaic release pattern. It does appear that there would be a difference between the two delivery systems for the delivery patterns to differ. Applicants have not provided that. Also applicants do not claim first and second bursts that are attributable to structural difference between the instant delivery system and the delivery system of the prior art.

8. Claims 1-3, 5-8, 10, 11, 13-15, 17-19, 21-23, 27-29, 32, 33, 35-37, 40, 42 and 44-50 remain rejected under 35 U.S.C. 102(b) as being anticipated by Pyo et al. (“Electrochemical Stimulated Adenosine 5'-Triphosphate (ATP) Release through Redox Switching of Conducting Polypyrrole Films and Bilayers,” Chem. Mater., vol. 8, (1996) pp. 128-133.

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Applicants argue that Pyo does not disclose or suggest that “its electrode is capable of a non Faradaic burst release and that the Office action “failed to produce evidence or scientific reasoning that a bi-layer electrode such as that disclosed in Pyo is necessarily capable of the burst release” of the examined claims.

9. Applicants' arguments filed 04/01/04 have been fully considered but they are not persuasive.

In the first instance, applicants failed to exclude bi-layer electrodes. Secondly, since Pyo's electrode does not require optimization in order for the electrode to release biologically active ingredients in a non-Faradaic release pattern/profile, the Examiner does not have to produce extrinsic evidence. More particularly, if the examined drug delivery system and the drug delivery system of Pyo are the same compositions comprising the same polymers containing biologically active ingredients, it stands to reason the two systems would have the same release profiles except one system differs from the other in ways that would ensure one release profile to be different from the other.

Claim Objections

Claim 6 remains objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

One acceptable form of multiple dependent claim would read “---as in any one of claims 1 and 2 ---.”

Suggestion:

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In line 2 of claim 31, it is suggested that the parenthesis be deleted and ---selected from the group consisting of--- be inserted after catecholamines.

It is respectfully noted that applicants have not addressed the objection to claim 6 and the suggestion for claim 31.

No claim is allowed.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Miller et al. (US 4,585,652) discloses controlled release delivery system that comprises electrochemically recyclable polymeric electrode upon which is loaded bioactive counter ions (abstract and column 2, lines 26-36). The bioactive counter ions are anionic or cationic or neutral (column 5, line 47 to column 6 line 35) and the polymeric body can have cationic sites (claim 3) or anionic sites (claim 5). Poly(pyrroles), substituted polythiophenes, poly(thiophenols), poly(aromatics), polyacetylenes are examples of polymers that can be employed in Miller (column 4, lines 15-68).

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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